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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,102	03/30/2004	Andrew A. Conway	208.1005.01	6571
22883 7590 03/22/2007 SWERNOFSKY LAW GROUP PC P.O. BOX 390013 MOUNTAIN VIEW, CA 94039-0013			EXAMINER AGRAWAL, RITESH	
			ART UNIT 1631	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 03/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/815,102

Applicant(s)

CONWAY, ANDREW A.

Examiner

Ritesh Agrawal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicants' amendment and request for reconsideration in the communication filed on 12/22/06 is acknowledged and the amendments entered.

Claims 1-8, 10-18, and 20-23 are currently pending and under consideration.

Withdrawn Rejections

2. The prior rejection of claims 1-8, 10-18, and 20 under 35 U.S.C. 101, a non-statutory rejection, is hereby withdrawn in light of applicant's amendments to the claims filed 12/22/06.

The prior rejection of claims 1-8, 10-20, and 22-23 under 35 U.S.C. 112, first paragraph, a new matter rejection, is withdrawn in light of applicant's amendments filed 12/22/06.

The prior rejection of claims 1-8, 10-18, and 20-23 under 112, 1st paragraph, an enablement rejection, is withdrawn in light of applicant's amendments filed 12/22/06.

The prior rejections of claims 1-8, 10-18, 20, and 22-23 under 35 U.S.C. 112, second paragraph, indefiniteness rejections, are withdrawn in light of the amendments filed 12/22/06.

The prior rejection of claims 21 under 35 U.S.C. 103, an obviousness rejection, is withdrawn in light of the amendments filed 12/22/06.

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Such sequence is present on page 7 of the specification. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a paper copy, a computer readable form of a Sequence Listing containing this sequence, and a statement under 37 CFR 1.821(f) are not provided. Applicants are given the same response time regarding failure to comply as that set forth to respond to this office action including providing a paper copy, a computer readable form of the Sequence Listing containing the sequence, and a statement under 37 CFR 1.821(f). Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 10-18, and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended independent claims 1, 11, and 21 to include the limitation "examining said marker scores to determine one or more contiguous regions of markers with a high sum of marker scores".

Applicant suggests support for this limitation on page 19, line 20 through page 21, line 6 (see remarks, page 9).

First, page 19, line 20, states that *merged scores* are examined to find a run of high scores. While between the specification and the claims it is unclear what a "merged score" is, earlier in the claim, a merged score represents just the combination of individual scores for being autozygous or not. Given this representation, a merged score is not a marker score and therefore the merged scores and not the marker scores are examined. Second, applicant's claim amendment is drawn to determining "one or more" contiguous regions. As quoted from line 20 on page 19, the method identifies "a run of high scores" and it is further stated that, "**the** contiguous run of scores with **the** highest sum is found." While lines 1-6 of page 21 do disclose the use of a "marker score," the outlined algorithm does not provide for the calculation of multiple runs as there is only a single variable for highest score and best region. For the algorithm to return multiple values, it would need a means for storing multiple values (e.g. an array of high scores and an array of best regions) or making multiple iterations through the array. Further, the disclosed algorithm does not calculate a "sum of marker scores." For example, the algorithm begins with an S value of 0 and an H value of 0. The marker score can be

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added to S, but if the marker score is zero or less, S is set to 0 as in step C (hence, that marker score is lost and cannot be summed with the next marker score). Furthermore, if the marker score is greater than 0, S is greater than 0, and, therefore greater than H, so S is set to the value of H as in step E (which is 0 as initialized), therefore S becomes 0 and, once again, the marker score value is lost and cannot be summed with next marker score. Since the ability to find the region(s) is dependent upon the ability to find high scoring segments, the disclosure does not explain how to find regions of markers with high sum of marker scores. There are, therefore, at least three elements of the new limitation that are not supported by applicant's original disclosure.

Additionally, applicant has amended the independent claims to recite the limitation of "reporting said at least one contiguous region likely to contain a recessive allele associated with said genetic disease or trait to a user of said computing device."

Applicant suggests support for this amendment on page 22, lines 13-14 (remarks, page 9).

However, the cited portion of the specification only discloses that, "embodiments of the invention can be implemented on a desktop or laptop computer with standard input and output interfaces." Since there is no disclosed embodiment for, "reporting at least one contiguous region" and the cited text only provides that the desktop or laptop process "embodiments of the invention", the cited text does not provide adequate support for the claim amendment.

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As addressed above, since the disclosure does not support finding consecutive regions based upon marker score, claim 7 represents new matter because of the amendments made to claim 6.

Since the disclosure does not support computing all sums from an array of marker scores, only merged scores (for example, see page 21, lines 3-5), claim 8 represents new matter in light of the amendments to claim 6.

Since the disclosure provides for determining a statistically significant gap for merged but not marker scores, claim 10 represents new matter in light of the amendments to claim 6.

Claim 10 has been amended to include the limitation "reported to a user" in line 4. As addressed above, since the disclosure does not provide proper support for this limitation, this represents new matter.

As addressed above, since the disclosure does not support finding consecutive regions based upon marker score, claim 17 represents new matter because of the amendments made to claim 16.

Since the disclosure does not support computing all sums from an array of marker scores, only merged scores (for example, see page 21, lines 3-5), claim 18 represents new matter in light of the amendments to claim 16.

Since the disclosure provides for determining a statistically significant gap for merged but not marker scores, claim 20 represents new matter in light of the amendments to claim 16.

Claim 20 has been amended to include the limitation "reported to a user" in line 4. As addressed above, since the disclosure does not provide proper support for this limitation, this represents new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 10-18, and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 11, and 21 have been amended to include the limitation "markers in said actual and estimated genotype data relative to each person for which actual genotype data was determined." The inclusion of the phrase "actual and estimated" makes the claims indefinite. Prior to this limitation, the claims recite the limitation that the markers are in regions of genomes of affected people. Since the claims do not require that the actual genotype data come from genomes of affected people, it is unclear how one could have markers in the actual genotype data when the actual genotype data is not obtained from affected people.

The newly added term "high sum of marker scores" in claims 1 (line 37), 11 (line 31), and 21 (line 27) is a relative term which renders the claim indefinite. The term "high sum of marker scores" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Without an explicit standard,

It is unclear what a "high sum of marker scores" represents. Does it represent the contiguous region with the highest score? If not, how does one set the cutoff point for high versus low sum?

Claim 4 has been amended to include the limitation "said marker score for a marker." As a marker has multiple marker scores, it is unclear as to which of these scores the limitation refers.

Claim 10 recites the new limitation "said sums" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to "sums" in claim 10, or the claims from which it depends.

Claim 14 has been amended to include the limitation "said marker score for a marker." As a marker has multiple marker scores, it is unclear as to which of these scores the limitation refers.

Claim 20 recites the new limitation "said sums" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to "sums" in claim 10, or the claims from which it depends.

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal, PhD 


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SUPERVISORY PATENT EXAMINER